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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/937,756	09/25/1997	DAVID C. RUEGER	JJJ-P06-504	2132

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Erika Takeuchi
ROPES & GRAY LLP
45 Rockefeller Plaza
New York, NY 10111-0087

EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 08/937,756	**Applicant(s)** RUEGER ET AL.	
	Examiner Chang-Yu Wang	**Art Unit** 1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *97,99 and 105-113*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:
The rejections of claims 97, 99, 105-111 under the judicially created doctrine of obviousness-type double patenting for being unpatentable over claims 1-8 of 6,288,031, claims 1-2 of 6,495,513, claims 1-16 of US 6,800,603, and claims 1-18 of 6,949,505 is withdrawn in response to Applicant's terminal disclaimer.

The rejection of Claims 97, 99, 105-113 under 35 U.S.C. 112, first paragraph, because the specification does not enable for the invention commensurate in scope with the claims is maintained for reasons of record in the previous office action. The amended claims 97 and 112 are directed to a method for decreasing neuronal cell death associated with a neuropathy comprising adminstering to a subject afflicted with a neuropathy associated with altered NCAM or L1 isoform levels a morphgen. Claims 99 and 113 are directed to a method for decreasing neuronal cell death associated with a chemical or physical injury comprsing administering to a subject having a neuron afflicted with a physical injury or who was exposed to a toxint resulting in a chemical injury a morphhogen. The rest of claims depend from claims 97, 99, 112 and 113.The amended claims 97 and 112 are not enabled because Applicant fails to provide sufficient guidance as to how a neuropathy is associated with an changed level of NCAM or L1 isoform since reduced NCAM or L1 isoform is associated with inhibiting neural development and an altered level of NCAM or L1 isoform could be an increased or decreased level of the expression. Thus, it is unpredicable whether adminstration of a morphogen could be used to decrease neuronal cell death in all forms of neuropathy caused by all forms of alteration of NCAM or L1. In addition, the amended claims 99 and 113 are not enabled because Applicant fails to provide sufficient guidance as to whether administration of a morphogen could be used to decrease neuronal cell death in all forms of chemical or physical injury since chemical injury also includes chemical burning by strong chemicals and physical injury also encompasses nerve injury of the CNS. Applicant only demonstrated that neuronal cell death caused by sciatic nerve injury (PNS) and ethanol could be reduced by administration of OP-1. Based on the prior art and specification, Applicant is enabled for reducing neuronal cell death derived from peripheral nerve injury and neuronal cell death caused by ethanol exposure. However, Applicant is not enabled for reducing neuronal cell death derived from nerve damage of the CNS or neurodegenerative diseases, which could be caused by different molecular mechanisms or all forms of chemical or physical injury caused by all types of toxins. Applicant fails to demonstrate that the chemical or physical injury caused by strong chemicals could be reversed by administration of a morphogen since the cell damage caused by these chemicals are permanent and the adult CNS nerve injury cannot be repaired. .

JANET L ANDRES
SUPERVISORY PATENT EXAMINER